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CLINICAL GUIDELINE

Guidelines on common cold for Traditional Chinese Medicine based on pattern differentiation

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Abstract

OBJECTIVE: To establish the guidelines on common cold treated with Traditional Chinese Medicine (TCM) in terms of pattern identification.

METHODS: The guidelines were formulated by using the basic patterns of common cold in China Pharmacopeia integrated with findings from systematic literature review and the experts' consensus on the issue in question.

RESULTS: Common cold was divided into four patterns in the guidelines. The medications were recommended respectively: Ganmaoqingre granule for wind-cold exterior syndrome, Yinqiaojiedu granule for wind-heat exterior syndrome, Huoxiangzhengqi Wan for summer-heat dampness exterior syndrome and Shensu Wan for wind-cold exterior syndrome accompanied with *Qi* deficiency.

CONCLUSION: The guidelines were primarily derived from the practice experience of TCM and the experts' consensus. The process was not strictly evidence-based because of lacking enough clinical studies. Further refinement of the guidelines should be needed as more studies are available.

Key words: Common cold; Practice guideline; Medicine, Chinese traditional; Pattern differentiation

INTRODUCTION

Common cold, often known as cold,[1] is an acute upper respiratory tract viral infection caused by rhinovirus, coronavirus, parainfluenza virus, respiratory syncytial virus (RSV) etc. It is the most common viral infection with a sporadic incidence and self-limiting nature. The often seen symptoms are nasal congestion, runny nose, sore throat, and cough. The natural course of the cold varies from 4 to 10 days, if no complications involve. Various complications may be present in a common cold including supurative pharyngitis, sinusitis, otitis

media, bronchitis, or acute progression or deterioration of underlying respiratory diseases. Probability of complications increases in the elderly, patients with chronic heart, lung, kidney or cerebral disorders or compromised immunity.

Up to now, no evidence-based guidelines have been published on common cold for clinical practice. Generations of Traditional Chinese Medicine (TCM) practitioners have developed quite a few formulas for the cold. They have been prepared in various forms such as tablet, pill, powder, capsule, and oral liquid etc specified by China Pharmacopeia.[2] The China Pharmacopeia 2010 documents 56 formulas for the cold.[3] Studies have demonstrated many ingredients or compounds of TCM remedy for common cold. They have the following effects: diaphoresis and antipyretic,[4,5] analgesic and tranquilizer,[6] cough suppressant,[5] anti-inflammation,[7,8] anti-microorganism,[7] antivirus[5,7,9] and immunoregulation.[7]

"TCM pattern or syndrome is an outcome of analysis of TCM information by TCM practitioner. Pattern classification is a traditional diagnostic method to categorize the patients based on their different conditions".[10] The treatment of common cold in TCM is based on pattern differentiation. According to TCM theory, common cold is considered as exterior syndrome, which can be further divided into the wind-cold, wind-heat and summer-heat dampness syndrome. Exterior syndrome in common cold is due to external contraction of pathogenic factors of wind-cold, wind-heat or summer-heat damp. Sometimes common cold occurred in the patients who suffer from other patterns. If a patient with *Qi* deficiency was exposed to wind-cold, this is the *Qi* deficiency syndrome complicated by exterior syndrome.

As clinical guidelines in modern times are made based on evidence, TCM guidelines on common cold shall also be derived from evidence, which was obtained from a systematic literature review. A guideline steering committee and its review group established by China Academy of Chinese Medical Science participated in reviewing and finalizing the guidelines. The evidence-based guidelines on common cold for clinical practice was published in 2011.[11]

MATERIALS AND METHODS

Literature retrieval

Literature in English were retrieved with the key word "common cold" in the following database from 1987 through 2009: on-line Medical Literature Analysis and Retrieval System, the Cochrane Library, Evidence-Based Medicine Reviews, Allied and Alternative Medicine -Allied and Complimentary Medicine database, The National Guideline Clearinghouse, etc.

Literature in Chinese were searched with the keyword 'Gan mao' (common cold in Chinese) and names of relevant experts in the following database from 1987 through 2009: China National Knowledge Infrastructure, Chinese Medicine Literature Database, Chinese Thesis Database, VIP Medicine Information System, Chinese Medical Current Contents, Founder Digital library and etc.

Literature in Japanese was retrieved manually from journals and electronically from databases. The journals were Kampo Medicine (1987-2007), Japan Oriental Medicine (1987-2007), Advancement of Kampo Medicine (1996-2005), Meridian and Acupuncture (1987-2007), Acupuncture Treatment (1991-2007), Japanese Medicine (1987-2007), Clinical Kampo Medicine (1997-2007), Journal of Japan Association of Acupuncture and Moxibustion (1987-2007), Clinical Medicine (1987-2007), Meiji Acupucnture and Moxibustion (1987-2007), Traditional Medicine (1998-2007), The Journal of Kampo Medicine & Pharmacy (1997-2002), Journal of Traditional Medicines (1987-2007), and Treatment (1987-2007), etc; the databases were, Scholarly and Academic Information Navigator, National Institute of Informatics, Meteo Inegrate, Sunmedica, JMEDPlus and International Medical Information Center, searched with the keywords of "common cold", "cold", "wind pathogen", "kampo medicine", "acupuncture and moxibustion" as of 31st, July, 2007.

Literature in Korean was retrieved with key words of "common cold", "toxin cold", "Korean medicine", "acupuncture and moxibustion etc in the Library of Seoul University and the Library of Kyung Hee University and in the Journal of Korean Epidemics Association, Journal of Korean Society of Pharmacognosy, Journal of Korean Society of Virology, Journal of Association of Korean Medicine and Life Sciences, Journal of Korean Society of Emergency Medicine, Journal of Korean Society of Microorganism, Korean Journal of Life Sceinces, Journal of Korean Society of Food Nutrition, Journal of Korean Society of Pharmacology, Journal of Korean Medicine Institute, Korean Health Care, Journal of Korean Society of Medicinal Herbs from 1987 up to 31, July, 2007.

Inclusion criteria

(a) Research design: randomized controlled clinical trial with or without blinding; (b) diagnosis criteria: diagnosis of common cold with biomedicine and/or Traditional Chinese Medicine criteria; with pattern differentiation. (c) intervention: oral administration of single herb or compound; (d) subjects ≥18 years.

Exclusion criteria

(a) Redundant publication (s); (b) subjects contracting influenza or pregnant subjects; (c) absence of TCM pattern differentiation.

Literature screening

All papers were screened by two experts independently.

Included papers were then assorted and appraised. When the two had a disagreement, a third party made the decision.

Levels of evidence

Evidence was divided into 5 levels.[12] Level Ia consisted of evidence obtained from consistent results from two different kinds of studies of the following: randomized controlled trial, cohort study, case-control study and case series. Level Ib consisted of evidences obtained from one well-designed randomize, controlled trial with sufficient power. Level IIa consisted of evidence obtained from cohort study. Level IIb consists of evidence obtained from case-control study. Level IIIa consisted of evidence obtained from case series with historical control. Level IIIb consisted of evidence obtained from case series with self before-after control. Level IV consisted of evidence obtained from case reports and therapies recorded in historical documents, which have undergone long time of clinical testing and application. Level V consisted of evidences obtained from expert committee reports or opinions and/or clinical experience of respected authorities without any systematic testing or evidence obtained from case reports and therapies recorded in historical documents, which have not undergone long time of clinical testing or application.

Expert consensus

For recommendation without sound evidence, if the expert panel agreed to use it in the guidelines, the drafting group would invite other experts to fully discuss to reach a consensus. That particular piece of recommendation would be used for expert consensus.

Recommended grading system

Grading system recommended by guideline Grading Work Group[13] by the US National Guideline Clearinghouse: grade A: at least one randomized control trial (RCT) as a part of literature evidence to provide consistent and high-quality recommendation (based on evidence of level Ia and Ib); grade B: well-conducted and relevant clinical studies yet without RCTs (based on evidence of level IIa, IIb and III); grade C: reports or consensus and/or clinical experiences from an expert committee with relevant high-quality clinical studies (based on evidence of level IV).

RESULTS

Literature quantity

Total of 2880 papers were identified and assigned into the following intervention categories: Chinese medicinal, acupuncture, other therapies and prevention.

No English or Korean literature was identified. Forty-two Chinese studies[14-55] were included with 2 abstracts of Japanese papers.[56,57] Forty-four randomized clinical trials were included into the final study.

A Cochrane systematic review[58] published in 2007 located 14 RCTs and graded them all as level C in terms of evidence quality.

Study design

(a) Randomization: stratified randomization, multi-center block randomization and envelop methods were reported. Thirty-four studies did not report details of their randomization methods. (b) Blinding: 4 studies claimed to have used single blinding methods yet failed to provide details. Twelve studies stated they had conducted double-blinding. Several of them didn't report blinding methods. All other studies didn't report whether they used blinding or not.

Criteria of diagnosis and differentiation

Diagnosis criteria of the included studies varied. The diagnosis criteria of the West Medicine were mainly from Practical Internal Medicine, etc.[59,60] The differentiation criteria of the TCM were mainly from TCM internal Medicine, etc.[61-65]

Intervention

In the RCTs with TCM treatment, the medications were either a decoction or a patent Chinese medicine with significant discrepancy in their formulas, which made it difficult to be categorized. Most of the control groups, however, also used either decoction or patent Chinese medicine. Six compared different preparation forms of TCM. Eleven used western medicines as the control. Only one in Japanese paper used placebo as control.

Study subjects

(a) Category of syndromes: 22 papers were on wind-heat exterior syndrome, 17 on wind-cold exterior syndrome, 3 on summer-heat dampness exterior syndrome and 2 on wind-cold exterior syndrome accompanied with *Qi* deficiency. (b) Source of cases: 16 papers reported their cases were from out-patient clinic while 7 papers from both out-and in-patient clinics. Twenty-one papers didn't report the source of cases. (c) Number of cases: 8330 subjects were identified in total; of them, 3616 were wind-heat exterior syndrome, 4000 wind-cold exterior syndrome, 576 summer-heat dampness exterior syndrome and 138 wind-cold exterior syndrome accompanied with *Qi* deficiency.

Expert consensus

A guideline drafting group was constituted and reached the following consensus:

(a) TCM treatment of common cold should be based on pattern differentiation; (b) pattern classification of common cold in the guidelines is categorized the same way as in the China Pharmacopeia; (c) the medications to be prescribed should be those specified in the pharmacopeia and supported by clinical studies.

Recommendation

Wind-cold exterior syndrome: clinical manifestation:

severe aversion to cold, mild fever, absence of sweating, headache, body ache, lassitude, lack of strength, nasal congestion with clear nasal discharge, sneezing, coughing with thin and white sputum, thin and white tongue coating, floating and tight or floating and moderate pulse. Treatment principle: to release the exterior with pungent-warm. Medications: either one of the following patent medicine (grade A, Level Ⅱa/Ⅱb); Ganmaoqingre granule[17] (relieving-cold and clearing-heat granule); Chailian oral solution[17] (oral liquid of *Radix Bupleuri* and *Fructus Forsythiae*); Gegen Tang[26] (*Radix Puerariae Lobatae* decoction); Jing Fang compound[21,26] (*Herba Schizonepetae* and *Radix Saposhnikoviae* compound).

Wind-heat exterior syndrome: clinical manifestation: fever, distending headache, nasal congestion with turbid nasal discharge, sore and swollen throat, aggravated by swallowing, coughing with yellow sputum and/or sputum difficult to expectorate, dry mouth and thirst, marginally red tongue, white or yellow tongue coating, floating and rapid pulse. Treatment principle: to release the exterior with pungent-cool. Medications: either one of the following patent medicine (Grade A, Level Ⅱa/Ⅱb). Yinqiaojiedu granule,[32] (antitoxin granule of *Fructus Forsythiae* and *Flos Lonicerae Japonicae*); Chaiguanjiere granule[32] (relieving-heat granule of *Radix Bupleuri* and *Rhizoma Dryopteridis Crassirhizomatis*); Shuanghuanglian oral solution[34] (oral liquid of *Flos Lonicerae Japonicae*, *Radix Scutellariae* and *Fructus Forsythiae*); Jinlianqingre capsule[38] (heat-clearing capsule of Chinese Globeflower); Qingjie oral solution[40] (heat clearing oral liquid).

Summer-heat dampness exterior syndrome: clinical manifestation: mostly seen in summer and autumn, fever, absence of sweating or mild sweating, general aching and lack of strength, distending dizziness and heaviness in the head, stuffy and runny nose, oppression in the chest and stuffiness in the stomach, nausea and vomiting, abdominal fullness and diarrhea, yellow and slimy tongue coating, soggy and rapid pulse. Treatment principle: to clear summer-hear, dispel dampness and release exterior. Medications (grade B, level Ⅱa/IV): Huoxiangzhengqi Wan[52] (*Herba Pogostemonis* pill).

Wind-cold exterior syndrome with *Qi* deficiency: clinical manifestation: chills and fever, or mild fever, spontaneous sweating, headache, nasal congestion, cough with whit sputum, low voice, shortness of breath, lassitude, lack of strength, thirst without desire to drink, lingered course with recurrent attacks of common cold, white tongue fur, floating and weak pulse. Treatment principle: to release exterior and tonify *Qi*. Medications (grade B, level Ⅱa/IV): Shensu Wan[14] (pill of Ginseng and Perilla leaf).

DISCUSSION

TCM has been making advances in the pattern differentiation for the treatment of common cold in the past two thousand years. The authors have tried to integrate evidence-based medicine into the drafting of guidelines on common cold for TCM treatment. As there is still no enough literature to provide sound evidence that meets the standards of modern evidence-based medicine, it seems quite difficult to formulate the guidelines that are totally consistent with tenet of evidence-based medicine.

Apart from the four syndromes mentioned above, following syndromes such as wind-damp exterior syndrome, wind-heat exterior syndrome accompanied with *Yin* deficiency, deserved further study. Currently, Guidelines for Clinical Studies on New TCM Drugs[62] uses a scale of four levels: totally recovered, significantly effective, effective and ineffective to measure outcome after three-day treatment. There are three outcome measurements: disease, syndrome and temperature, all of which are based on symptom scoring. We propose that symptom relief and its timing should be the major outcome measured to demonstrate instant symptom relief and duration reduction. Follow-up should be conducted to evaluate the incidence of cough after suffering from cold, suppurative pharyngitis, sinusitis and otitis media in order to investigate whether TCM could reduce the incidence of complications and provide a bigger picture for TCM's efficacy.

As the treatment course is fairly short in common cold and there has been few reports on adverse events. Safety evaluation should be, nonetheless, incorporated into clinical trials on common cold.

The medications recommended in this guideline have been in wide use for a long period of time yet without evidence of modern sense. With the improvement of TCM research and methodology, more good quality studies are to be conducted to update and refine the guidelines.

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